

**Notice of Allowability**

Application No.

10/715,810

Applicant(s)

LI ET AL.

Examiner

Chih-Min Kam

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 7/13/00.
2. ☒ The allowed claim(s) is/are 1,5-7,9-11,18-21 and 76-80.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

- |  |   |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)   | 5. <input type="checkbox"/> Notice of Informal Patent Application                     |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 6. <input type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),<br>Paper No./Mail Date _____    | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                   |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance  |
|  | 9. <input type="checkbox"/> Other _____   |

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1, 5-7, 9-11, 18-21 and 76-80 are pending.

Applicants' amendment filed July 13, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1 and 76 have been amended, and claim 75 has been cancelled. Therefore, claims 1, 5-7, 9-11, 18-21 and 76-80 are examined.

### ***Correction of Inventorship***

2. In view of the papers filed July 13, 2006, it has been found that this nonprovisional application, as filed, through error and without deceptive intent, improperly set forth the inventorship, and accordingly, this application has been corrected in compliance with 37 CFR 1.48(a). The inventorship of this application has been changed by addition of Lance E. Steward and Joseph Francis.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

### **Withdrawn-Informalities**

3. The previous objection to the specification, regarding Fig. 2 and Sequence Listing, is withdrawn in view of applicants' amendment to the specification and applicants' submission of a new Fig. 2 and Sequence Listing in the amendment filed July 13, 2006. CRF has been entered.

### **Withdrawn Claim Rejections - 35 USC § 112**

5. The previous rejection of claims 1, 5-7, 9-11, 18-21 and 75-80, under 35 U.S.C. 112, second paragraph, is withdrawn in view of applicants' amendment of the claim, applicants'

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cancellation of the claim, and applicants' response at page 8 in the amendment filed July 13, 2006.

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**Examiner's Amendment**

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

**Examiner's Amendments to the specification:**

Please replace paragraph [0041] at pages 13 and 14 with the following paragraph:

Figure 10 shows the amino acid sequence (SEQ ID NO:4) for iBoNT/A-Hall (Allergan) (H227Y)- His6 baculovirus expression vector system (rec-iBoNT/A (H227Y)-His6). This rec-iBoNT/A is recognized by Anti-Toxin polyclonal antibody.

**The following is an Examiner's Statement of Reasons for Allowance:** The following references appear to be the closest art to the claimed invention. Kiyatkin *et al.* (Infection and Immunity Vol. 65, No. 11, 4586-4591, 1997) teach modified recombinant botulinum toxins serotype C having three amino acid mutations (H229G, E230T and H233N) in the zinc-binding motif were generated and resulted in complete detoxification of the modified recombinant holotoxins. Modified recombinant holotoxins are not toxic to mice, both oral administration and subcutaneous administration of modified recombinant neurotoxin evoked high levels of serum antibodies and protective immunity; and Simpson *et al.* (U.S. Patent 6,051,239; published on April 18, 2000) teach a modified recombinant botulinum toxin having a mutation in the zinc-binding motif, His-Glu-X-X-His, can be used as oral vaccine for antigenic peptides including botulinum toxin and for the oral delivery of other therapeutic agents to the general circulations. However, the references do not teach the use of a glycosylated inactive botulinum toxin to treat a botulinum toxin intoxication. Therefore, the claims are allowable over the art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

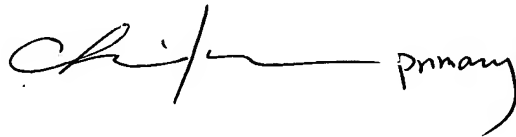
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4.30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.  
Primary Patent Examiner

A handwritten signature in black ink, appearing to read 'Chih-Min Kam', followed by the word 'primary' written in a cursive script.

**CHIH-MIN KAM**  
**PATENT EXAMINER**

CMK

September 25, 2006